510(k) Summary K090827

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BD ProbeTec™ *Neisseria gonorrhoeae* (GC) Q^x Amplified DNA Assay

Applicant	BD Diagnostic Systems 7 Loveton Circle Sparks, MD 21152
	MAY 27 2009
Establishment Registration No.	1119779
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Summary Date	March 25, 2009
Proprietary Name	BD ProbeTec™ *Neisseria gonorrhoeae* (GC) Q^x Amplified DNA Assay
Generic Name	DNA Reagents, Neisseria
Classification	Class II
Classification Name	Neisseria spp. direct serological test reagents
Regulation Number	866.3390
Product Code	LSL
Predicate Devices	BD ProbeTec™ *Neisseria gonorrhoeae* (GC) Q^x Amplified DNA Assay (K081825), Gen-Probe APTIMA Assay for *Neisseria gonorrhoeae* (AGC) (K062440)

Device Description

The **BD ProbeTec** GC Q^x Amplified DNA Assay is based on the simultaneous amplification and detection of target DNA using amplification primers and a fluorescently-labeled detector probe. The reagents for SDA are dried in two separate disposable microwells: the Priming Microwell contains the amplification primers, fluorescently-labeled detector probe, nucleotides and other reagents necessary for amplification, while the Amplification Microwell contains the two enzymes (a DNA polymerase and a restriction endonuclease) that are required for SDA. The **BD Viper™ System** pipettes a portion of the purified DNA solution from each Extraction Tube into a Priming Microwell to rehydrate the contents. After a brief incubation, the reaction mixture is transferred to a corresponding, pre-warmed Amplification Microwell which is sealed to prevent contamination and then incubated in one of the two thermally-controlled fluorescent readers. The presence or absence of *N. gonorrhoeae* DNA is determined by calculating the peak fluorescence

(Maximum Relative Fluorescent Units (MaxRFU)) over the course of the amplification process and by comparing this measurement to a predetermined threshold value.

In addition to the fluorescent probe used to detect amplified *N. gonorrhoeae* target DNA, a second labeled oligonucleotide is incorporated in each reaction. The Extraction Control (EC) oligonucleotide is labeled with a different dye than that used for detection of the *N. gonorrhoeae* -specific target and is used to confirm the validity of the extraction process. The EC is dried in the Extraction Tubes and is rehydrated upon addition of the specimen and extraction reagents. At the end of the extraction process, the EC fluorescence is monitored by the **BD Viper System** and an automated algorithm is applied to both the EC and *N. gonorrhoeae* -specific signals to report results as positive, negative, or EC failure.

Intended Use

The BD ProbeTec™ *Neisseria gonorrhoeae* (GC) Q^x Amplified DNA Assay, when tested with the BD Viper™ System in Extracted Mode, uses Strand Displacement Amplification technology for the direct, qualitative detection of *Neisseria gonorrhoeae* DNA in clinician-collected female endocervical and male urethral swab specimens, patient–collected vaginal swab specimens (in a clinical setting), and male and female urine specimens (both UPT and Neat). The assay is also intended for use with gynecological specimens collected in PreservCyt® Solution using an aliquot that is removed prior to processing for additional gynecological testing. The assay is indicated for use with asymptomatic and symptomatic females and symptomatic males to aid in the diagnosis of gonococcal urogenital disease.

Summary and Principles of Operation

When used with the **BD Viper System**, the **BD ProbeTec** GC Q^x Amplified DNA Assay involves automated extraction of DNA from clinical specimens through the chemical lysis of cells, followed by binding of DNA to para-magnetic particles, washing of the bound nucleic acid and elution in an amplification-compatible buffer. When present, *N. gonorrhoeae* DNA is then detected by Strand Displacement Amplification (SDA) of a specific target sequence in the presence of a fluorescently labeled detector probe.

Analytical Performance Characteristics

Limit of Detection (Analytical Sensitivity)

The Limits of Detection (LODs) for the GC Q^x Assay with *Neisseria gonorrhoeae* strain ATCC 19424 in PreservCyt specimens when extracted on the **BD Viper System** were determined to be ≤ 100 GC cells per mL. The GC Q^x Assay on the **BD Viper System** in extracted mode was able to detect 17 GC strains with ≥ 95% proportion positive at a concentration of 50 cells per mL in clean diluted PreservCyt Solution.

Interfering Substances
Potential interfering substances which may be encountered in PreservCyt specimens were extracted from diluted PreservCyt matrix in the absence and presence of GC target (300 GC cells/mL) and tested with the **BD ProbeTec** GC Q^x Amplified DNA Assay on the **BD Viper System**. Results are summarized in **Table 2.**

Table 2 Interfering Substances

Interpretation	PreservCyt
No Interference Observed	Blood (≤ 1%) Seminal Fluid Mucus Over The Counter vaginal products and contraceptives Hemorrhoidal cream Prescription vaginal treatments Leukocytes ($1x10^6$ cells/mL) $1x10^6$ EB/mL *Chlamydia trachomatis*
May cause extraction control (EC) failures	Glacial Acetic Acid + Blood (≤5%/1% V/V)
May cause False Negative results	Glacial Acetic Acid + Blood (≤5%/1% V/V)

Clinical Performance Characteristics

Endocervical swab specimens and PreservCyt specimens were collected from 2079 compliant female subjects attending family planning, OB/GYN, and sexually transmitted disease clinics at eleven geographically diverse clinical sites in North America. Subjects were classified as symptomatic if they reported symptoms such as dysuria, coital pain/difficulty/bleeding, abnormal vaginal discharge, or pelvic/uterine/adnexal pain. Subjects were classified as asymptomatic if they did not report symptoms. Two subjects were excluded due to an undetermined patient infected status. Three subjects did not have a PreservCyt specimen result. Therefore there were 2074 subjects evaluated.

Three randomized endocervical swab specimens and a PreservCyt specimen were collected from each female subject. The three reference endocervical swabs were tested with the **BD ProbeTec** ET CT/GC/AC assay, the **BD ProbeTec** GC Q^x assay, and another commercially available NAAT (Nucleic Acid Amplification Test). Sensitivity and specificity for **PreservCyt** specimens were calculated by comparing results to a patient infected status (PIS) algorithm. The designation of positive or negative PIS was based on the endocervical swab specimen results

from the three reference methods. At least two positive reference results were required to establish a subject as PIS-positive. At least two negative reference results were required to establish a subject as PIS-negative. Sensitivity and specificity by symptomatic status are presented in Table 4.

The distribution of cervical sampling devices used in the clinical study according to clinical collection site is summarized in Table 3.

Table 3 Summary of Cervical Sampling Devices Used in the PreservCyt Specimen Clinical Study

Cervical Sampling Device Used	Clinical Collection Site Number											Total
	2	3	4	5	6	7	8	9	10	11	12	
Broom-Type Device	89	0	0	45	16	464	272	83	0	99	0	1068
Spatula/Cytobrush	74	154	95	0	0	52	0	209	282	0	145	1011

Table 4 GC Q^x^ Assay Performance for PreservCyt Specimens Compared to Patient Infected Status (by symptomatic status)

		Performance Compared to Patient Infected Status						
Symptomatic Status	n	Sensitivity	95% C.I.	Specificity	95% C.I.	PPV%	NPV%	Error Initial/Final
A	1349	92.3% (24/26)	(74.9% - 99.1%)	100.0% (1323/1323)	(99.7% - 100.0%)	100.0%	99.9%	1/0
S	725	100.0% (17/17)	(80.5% - 100.0%)	99.9% (707/708)	(99.2% - 100.0%)	95.9%	100.0%	0/0
Total	2074	95.3% (41/43)	(84.2% - 99.4%)	99.95% (2030/2031)	(99.7% - 100.0%)	100.0%	99.9%	1/0

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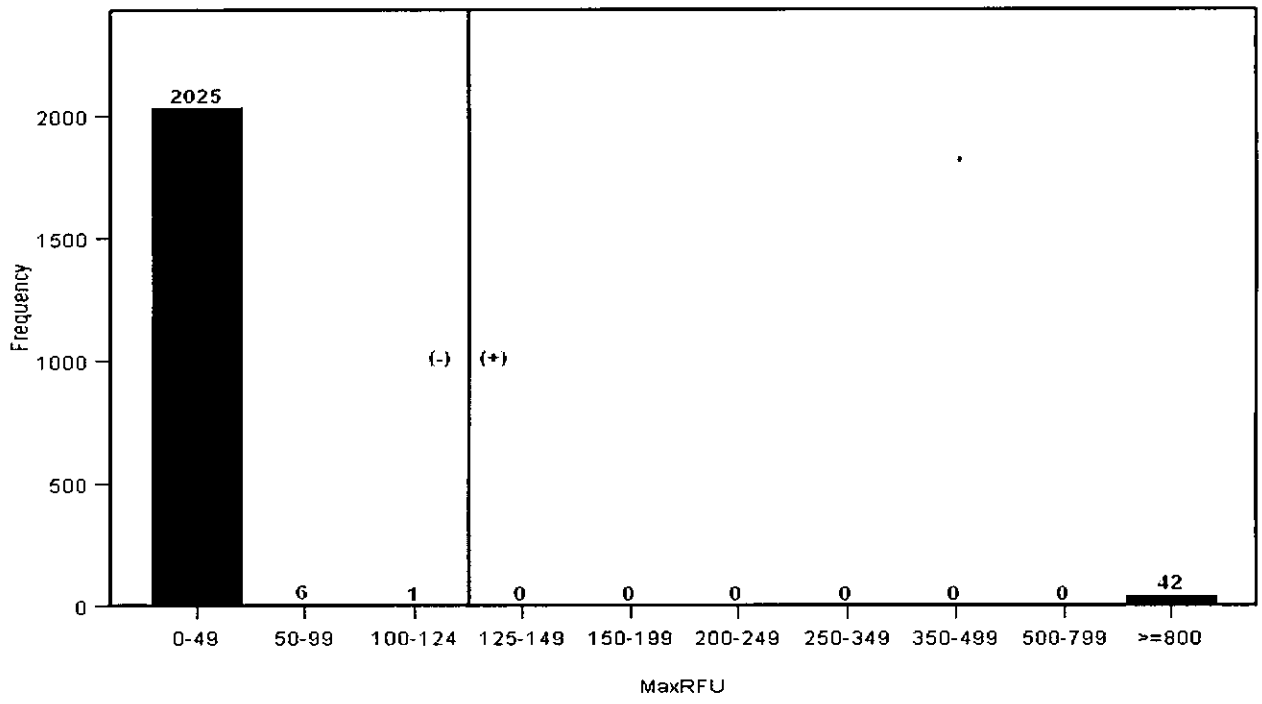
A total of 2074 GC Q^x Assay results from PreservCyt specimens was evaluated from eleven geographically diverse clinical sites. A frequency distribution of the initial MaxRFU values for the GC Q^x assay is shown in Figure A..

Figure A **Frequency Distribution of MaxRFU for the GC Q^x Assay (PreservCyt Specimens)**



Reproducibility

A reproducibility study of the **BD Viper** System using the **BD ProbeTec** GC Q^x Assay was evaluated for Liquid Based Cytology (LBC) specimens at three clinical sites on one **BD Viper** System per site. A panel of simulated specimens comprising CT and GC organisms seeded into LBC Specimen Dilution Tubes containing LBC medium was tested with the **BD ProbeTec** GC Q^x Assay. Uninoculated LBC Specimen Dilution Tubes containing LBC medium were used for the GC negative samples. Nine replicates of each panel member were tested every day for five days on each **BD Viper** System. The data are summarized in Table 5.

Two additional levels were included in the panels to characterize the reproducibility of test results (i.e., proportion positive or negative) at target levels below the analytical Limit of Detection (LOD) of the **BD ProbeTec** GC Q^x Assay. These additional specimens comprised CT and GC organisms seeded into LBC Specimen Dilution Tubes containing LBC medium at dilutions of 1:10 and 1:100 of the respective analytical LODs of each analyte. These levels were selected to fall within the dynamic range of the analytical LOD curves for the **BD ProbeTec** CT Q^x and GC Q^x assays. Nine replicates of each panel member were tested every day for five days across the three **BD Viper** Systems. The data are summarized in Table 6.

Table 5 Summary of Reproducibility Data for LBC Specimens on the BD Viper System for the GC Q^x Assay

					Within Run		Between Runs Within Site		Between Site	
CT EB's/mL	**GC Cells/mL**	**% Correct**	**95% CI**	**Mean MaxRFU**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**
0	0	100.0% (135/135)	(97.3% - 100.0%)	1.21	4.00	330.38	0.00	0.00	0.00	0.00
30	0	100.0% (135/135)	(97.3% - 100.0%)	0.98	7.47	761.30	0.00	0.00	0.17	17.04
0	100	100.0% (135/135)	(97.3% - 100.0%)	1982.77	83.92	4.23	0.00	0.00	0.00	0.00
30	250	100.0% (135/135)	(97.3% - 100.0%)	1983.66	87.76	4.42	0.00	0.00	24.80	1.25
75	100	100.0% (135/135)	(97.3% - 100.0%)	1920.14	81.94	4.27	59.45	3.10	0.00	0.00

Table 6 Characterization of System Reproducibility at Target Levels below the Analytical Limit of Detection for the GC Q^x Assay for LBC Specimens

Dilution of Analytical LOD	% Positive	95% CI (Positive)	MaxRFU Mean (Positive)	% Negative	95% CI (Negative)	MaxRFU Mean (Negative)
1:10	74.1 (100/135)	(65.8 - 81.2)	1159.2	25.9 (35/135)	(18.8 - 34.2)	21.2
1:100	8.9 (12/135)	(4.7 - 15.0)	1136.5	91.1 (123/135)	(85.0 - 95.3)	6.6

Conclusions

The analytical and clinical study results for the **BD ProbeTec** *Neisseria gonorrhoeae* (GC) Q^x Amplified DNA Assay with PreservCyt specimens support the determination of substantial equivalence in accordance with the intended use as stated in the product labeling.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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MAY 27 2009

Ms. Saba Modjarrad
Regulatory Affairs Specialist
BD Diagnostics Systems
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Re: k090827
Trade/Device Name: BD ProbeTec™ *Neisseria gonorrhoeae* (GC) Q^X Amplified DNA Assay
Regulation Number: 21 CFR 866.3390
Regulation Name: Neisseria spp. direct serological test reagents
Regulatory Class: Class II
Product Code: LSL
Dated: March 25, 2009
Received: March 26, 2009

Dear Ms. Modjarrad:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at 240-276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k090827

Device Name: BD ProbeTec™ *Neisseria gonorrhoeae* (GC) Q^x Amplified DNA Assay

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The BD Viper System, when used with the BD ProbeTec amplified nucleic assay(s), is intended for the *in vitro* detection of targeted organisms from specimens as identified in the assay-specific reagent package insert(s).

Prescription Use ___√___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Uwe Scherf

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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